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10/042,258	01/11/2002	James Samsoondar	213202.00358	6989

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT PAPER NUMBER

1743

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/042,258

Applicant(s)

SAMSOONDAR, JAMES

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/958,933.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

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1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: It should claim priority to U.S. application serial number 09/958,933 under 35 USC 120, not USC 119, since this is not a foreign application. In addition, priority to US provisional application serial no. 60/133,876 should be claimed under 35 USC 119(e).

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprises" and "comprise". Correction is required. See MPEP § 608.01(b).

4. The disclosure is objected to because of the following informalities: On page 1, line 4 of the specification after the phrase "application 09/958,933 filed on May 11, 2000", the following phrase should be inserted so as to update the status of the parent application: --, now US Patent no. 6,582,964, issued on June 24, 2003--. On page 1, line 4 of the specification, the phrase "claiming priority" should be changed to --which claims priority--so as to make proper sense.

Appropriate correction is required.

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5. Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 2 of claim 1, the phrase "adapted to permit" is indefinite since it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. See *In re Hutchison*, 69 USPQ 138. See this same problem with the phrase "capable of" on line 2 of claims 6-7, with the phrase "adapted to permit" on lines 2 and 7 of claim 12, with the phrase "capable of" on line 2 of claims 17 and 18, with the phrase "adapted to reflect" on line 2 of claim 24 and with the phrase "adapted to transmit" on line 2 of claim 25. Claim 1 is also indefinite since it is unclear where the cover plate is located in relation to the base plate and well. There is no structural cooperation between the cover plate, the base plate and well. Is the cover plate located over the well? See this same problem in claim 25.

In claim 6, the phrase "said containment wall" lacks antecedent basis since claim 6 depends from claim 4, and claim 3 positively recites the containment wall. See this same problem in claim 9. Claim 6 is also indefinite since it is not clear where the circular ring is located. On the cover plate? See this same problem in claim 17.

On line 2 of claim 17, the phrase "said containment wall" lacks antecedent basis since claim 17 depends from claim 12, and claim 13 positively recites the containment wall.

Claim 20 is indefinite since it recites closing the cover plate over the well. However, claim 1, from which claim 20 depends, does not positively recite the cover plate being located over the well.

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In claim 24, the location of the cover plate in relation to the well is unclear. There is no structural cooperation between the cover plate and well. Does the cover plate serve to close the well when in the closed position?

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 20 and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Valencia.

Valencia teaches of a transparent microscope slide 10 made of a glass plate having a plurality of structurally defined retaining areas 12 spaced apart from one another. Each retaining area 12 is defined by a first boundary 16 comprising a closed wall and forming a test well 18, and a second boundary 20 comprising a closed wall and forming a channel 22. The channel 22 acts as a moat by confining any liquid spilling from the test well 18 within the retaining area 12. This serves to reduce the likelihood of cross-contamination among the separate liquid specimens on the slide. A thin transparent overslip (i.e. cover plate) is pressed gently onto the slide, and the entire coverslip-slide combination is placed under a microscope for visual examination. The slide retaining area or stage on a microscope constitutes a horizontal plane, and when light is projected through the slide on the microscope, electromagnetic radiation is passed perpendicular to the horizontal plane of the microscope stage. The recitation of the permission for either the transmission or reflection of electromagnetic radiation by the base plate and cover plate in the instant claims is merely for an intended use of the sample tab. A recitation with respect to the

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manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the structural limitations of that claimed.

See *In re Yabnush*, 477 F. 2d 1028, 168 USPQ 530 (CCPA 1971).

8. Claims 1-2, 4, 6, 8, 12, 17, 19 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Valkenburg.

Van Valkenburg teaches of a device for collecting blood. The device comprises a bowl or well 14 that is preferably formed with a plate member 18. The bowl 14 constitutes a closed wall extending above the surface of the plate member 18. A cap 27 can be hingedly attached by a strap 27s to either a collection tube 24 in which the device is inserted or to the device itself. See the embodiment depicted in Figures 8 and 10. The cap 27 comprises a locking member in the form of a circular ring that frictionally engages an outer wall of the bowl or well 14. See Figures 1 and 2 of Van Valkenburg. Van Valkenburg teaches that the cap 27 serves to prevent any blood within a collection tube 24 from escaping from the tube and contaminating a user of the device or any surfaces nearby. See lines 11-19 in column 5 of Van Valkenburg.

The recitation of the permission for either the transmission or reflection of electromagnetic radiation by the base plate and cover plate in the instant claims is merely for an intended use of the sample tab. A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the structural limitations of that claimed. See *In re Yabnush*, 477 F. 2d 1028, 168 USPQ 530 (CCPA 1971). The device taught by Van Valkenburg may be able to transmit or reflect electromagnetic radiation depending upon the material that it is manufactured from and its intended use.

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9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-2, 4, 6, 8, 12, 17, 19 and 20-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin et al in view of Van Valkenburg. For a teaching of Van Valkenburg, see previous paragraphs in this Office action.

Gavin et al teach of a blood sampling device, which comprises a cuvette 12 and a testing device 14 into which the cuvette 12 is inserted in a horizontal plane for analysis. The cuvette 12 is a planar structure made from a transparent material. The base of the cuvette 12 contains a supply reservoir 40 thereon. This reservoir 40 is a cup-like structure having an open top 44. A person using the device will prick his/her finger and place the finger over the supply reservoir to supply a blood sample to the cuvette 12. Blood travels from the supply reservoir 40 to a plurality of conduits in the cuvette that each contains a reagent to react with the blood. The cuvette 12 is then placed horizontally into a channel 54 of the testing device 14. A plurality of photoelectric sensors 61 are positioned on one side of the channel 54 directly across from light sources 53.

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The photoelectric sensors and light sources are positioned to direct light perpendicularly to each of the conduits in the cuvette. Light emissions from the light sources to the sensors pass through the transparent material of the cuvette 12 and the conduits therein. See Figures 1, 2 and 3a of Gavin et al. Gavin et al fail to teach that the supply reservoir 40 on the cuvette 12 has a cover hingedly attached to the planar portion of the cuvette.

Based upon the combination of Gavin et al and Van Valkenburg, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the supply reservoir 40 on the cuvette 12 taught by Gavin et al with a cover, similar to the cover hingedly attached to the bowl or well on the blood collection device taught by Van Valkenburg, since Van Valkenburg teaches that it is important to cover a supply well in a blood collection receptacle after collection in order to prevent any blood within the receptacle from escaping and contaminating a user of the device or any surfaces nearby, including the surfaces of the testing device 14 into which the cuvette 12 disclosed by Gavin et al is inserted.

12. Claims 7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin et al in view of Van Valkenburg as applied to claims 1-2, 4, 6, 8, 12, 17, 19 and 20-26 above, and further in view of Kitrilakis et al. For a teaching of Gavin et al and Van Valkenburg, see previous paragraphs in this Office action. Gavin et al and Van Valkenburg fail to teach of covering a supply well on a blood collection receptacle with a cover that has clips thereon for engaging with the material of the receptacle.

Kitrilakis et al teach of a device for collecting a blood sample for analysis that comprises a base plate 52 having a recess therein. The plate 52 has a flexible hinge 53 attached to a cover 54 that serves to cover the recess. The cover is held in a closed position by a locking member in

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the form of a spring catch 56 operating through an opening 57 in the base plate 52. When the catch is released, the cover 54 can be swung out of the way or to one side of the plate 52. See the embodiment in Figure 6 of Kitrilakis et al.

Based upon the combination of Gavin et al, Van Valkenburg, and Kitrilakis et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the supply reservoir 40 on the cuvette 12 taught by Gavin et al with a cover, similar to the cover hingedly attached to the bowl or well on the blood collection device taught by Van Valkenburg, for the reasons given above, and it further would have been obvious to one of ordinary skill in the art to provide the cover with a locking means comprising a clip or catch for engaging with the cuvette 12, similar to the locking means taught by Kitrilakis et al, since Kitrilakis et al teach that a spring catch or clip is one conventional means of securing a cover over a blood collection receptacle that is equivalent in function to the frictional engagement of the cover with the blood collection receptacle taught by Van Valkenburg.

13. Claims 1-6, 8-17, 19 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kheiri in view of Van Valkenburg. For a teaching of Van Valkenburg, see previous paragraphs in this Office action.

Kheiri teaches of a blood sample collection and test device, which comprises an elongated substrate 12 with a semicrater 14 located at one end. The semicrater 14 has a raised portion 16 constituting one side and a lower portion 18 on an opposite side. The semicrater 14 surrounds a sample application site 20. In use, a drop of blood is applied to the sample application site 20. Kheiri teaches that if desired, the semicrater can be covered by a shield to protect the sample application site 20. See lines 54-63 in column 3 of Kheiri. The substrate 12

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can be made from a transparent clear plastic, which permits any color development in the device to be observed either visually or with the help of an instrument that directs a beam of light onto the sample application site 20.

In another embodiment taught by Kheiri, the semicrater is surrounded by a raised rib 41 or 51. See Figures 4 and 5. These ribs are present to contain excess sample. Kheiri fails to teach that the semicrater on the cover has a cover hingedly attached to the substrate.

Based upon the combination of Kheiri and Van Valkenburg, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the semicrater on the substrate taught by Kheiri with a cover, similar to the cover hingedly attached to the bowl or well on the blood collection device taught by Van Valkenburg, since Kheiri provides the suggestion to include a cover over the semicrater and Van Valkenburg teaches that it is important to cover a supply well in a blood collection receptacle after collection in order to prevent any blood within the receptacle from escaping and contaminating a user of the device or any surfaces nearby, including the surfaces of a light emitting instrument into which the device taught by Kheiri may be inserted for analysis. It also would have been obvious to one of ordinary skill in the art to provide the ribs 41 and 51 taught by Kheiri with a sealing member such as an O-ring thereon so as to further seal a cover over the semicrater and form a tight seal against blood leakage.

14. Claims 7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kheiri in view of Van Valkenburg as applied to claims 1-6, 8-17, 19 and 24-25 above, and further in view of Kitrilakis et al. For a teaching of Kheiri, Van Valkenburg and Kitrilakis et al, see previous paragraphs in this Office action. Kheiri and Van Valkenburg fail to teach of covering a supply

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well on a blood collection receptacle with a cover that has clips thereon for engaging with the material of the receptacle.

Based upon the combination of Kheiri, Van Valkenburg, and Kitrilakis et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the semicrater on the substrate taught by Kheiri with a cover, similar to the cover hingedly attached to the bowl or well on the blood collection device taught by Van Valkenburg, for the reasons given above, and it further would have been obvious to one of ordinary skill in the art to provide the cover with a locking means comprising a clip or catch for engaging with the substrate, similar to the locking means taught by Kitrilakis et al, since Kitrilakis et al teach that a spring catch or clip is one conventional means of securing a cover over a blood collection receptacle that is equivalent in function to the frictional engagement of the cover with the blood collection receptacle taught by Van Valkenburg.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Kiser et al, Raman, Meyer, Kanda, Cinqualbre and Parham et al (EP 376,135) who all teach of different types of blood collection devices.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

February 23, 2004

Maureen M. Wallenhorst
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PRIMARY EXAMINER
GROUP ~~1200~~ 1700